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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,604	04/08/2004	Michel Gilbert	019633-000129US	1518
20350 7590 10/18/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER SWOPE, SHERIDAN	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/821,604	GILBERT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 43 and 46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>0407</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Applicants' response on October 12, 2007, to the First Action on the Merits of this case mailed October 27, 2006 and the non-responsive of July 16, 2007, is acknowledged. It is acknowledged that applicants have cancelled Claims 44, 45, 46, and 47-51 and amended Claim 43. Claims 43 and 46 are pending and are hereby considered.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

***Utility***

Claim 43 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Applicants have asserted, in said claims, that the elected polypeptide, having  $\beta$ 1,4-N-acetylglucosaminyl transferase activity, is encoded a *Campylobacter* nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41. The claims, specification, and the prior art fail to provide any evidence that supports said assertion. The instant disclosure does not teach a polypeptide having  $\beta$ 1,4-N-acetylglucosaminyl transferase activity or any polynucleotide that encodes such a polypeptide. Moreover, the Office failed to find evidence in the art that any *Campylobacter* cell expresses  $\beta$ 1,4-N-acetylglucosaminyl transferase activity. Therefore, the elected invention does not have a specific and substantial patentable utility.

Claim 43 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-

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established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 46 is rendered indefinite by being dependent from a cancelled claim.

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Enablement**

Even if Claim 43 was not rejected under 35 U.S.C. 101/112, for the reasons described above, the following rejection would be made.

Rejection of Claim 43 under 35 U.S.C. 112, first paragraph lack of enablement, is maintained. The reasons are identical to those explained in the prior action for rejection of Claims 49-51 under 35 U.S.C. 112, first paragraph lack of enablement. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) The rejection describes the state of the art before the time of filing, not considering the teachings of the specification. The Application is the first disclosure of a  $\beta$ 1,4N-GalNac

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transferase encoded by the *C. jejuni* LOS locus. Five such  $\beta$ 1,4N-GalNac proteins are disclosed as well as assays therefore (pgs 20, 23-24, and 50).

(B) The invention is enabled because high-through put assays for  $\beta$ 1,4N-GalNac activity are known in the art.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: The Office has considered the disclosure. Page 20 does not disclose the structure of any  $\beta$ 1,4N-GalNac protein. It is acknowledged that pages 23-24 assert that the protein of SEQ ID NO: 17 is a  $\beta$ 1,4N-GalNac protein; however, said pages provide no evidence in support of said assertion. It is acknowledged that page 50 describes an assay for  $\beta$ 1,4N-GalNac. However, no  $\beta$ 1,4N-GalNac protein encoded by a polynucleotide that can be PCR'd with SEQ ID NO: 40 and 41 is disclosed.

(B) Reply: It is acknowledged that assays for  $\beta$ 1,4N-GalNac activity are known in the art. However, the specification fails to enable the skilled artisan to make and use the full scope of the recited invention because it does not establish: (A) the structure of any protein having any  $\beta$ 1,4-N-acetylglucosaminyl transferase activity, wherein the protein is encoded by a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from and *Campylobacter* cell; (B) the structure of any polynucleotide that encodes a protein having or  $\beta$ 1,4-N-acetylglucosaminyl transferase activity, wherein the polynucleotide can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from and *Campylobacter* cell; (C) the specific type of glycosyltransferase activity of all proteins that are encoded by any polynucleotide that can be generated from any *Campylobacter* cells using the recited primers; (D) which *Campylobacter* cells can be used with the recited primers to generate

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nucleic acid molecules encoding proteins with the desired activity; (E) a rational and predictable scheme for isolating proteins with the desired activity; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### **Written Description**

Claims 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 43 is directed to a genus of proteins having  $\beta$ 1,4-N-acetylglucosaminyl transferase activity, wherein the protein is encoded a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any *Campylobacter* cell. The specification teaches the structure of no representative species of such proteins or nucleic acid molecules. Moreover, the specification fails to describe any species by any identifying characteristics or properties other than the functionality of the protein having  $\beta$ 1,4-N-acetylglucosaminyl transferase activity and the nucleic acid molecule encoding said protein. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear,

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concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

***Allowable Subject Matter***

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

**Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants'

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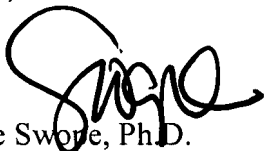
remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sheridan Lee Swope, Ph.D.  
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